Registration Decision RD2013-17

d-Phenothrin

(publié aussi en français)

29 August 2013

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

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ISSN: 1925-0932 (print)
1925-0940 (online)

Catalogue number: H113-25/2013-17E (print version)
H113-25/2013-17E-PDF (PDF version)

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Registration Decision for d-Phenothrin

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of Sumithrin Technical Grade (containing the active ingredient d-phenothrin) and eight domestic end-use products: four products containing d-phenothrin (Hartz UltraGuard Flea & Tick Treatment for Dogs and Puppies weighing either 2.5–6 kg, 6–14 kg, 14–28 kg, or greater than 28 kg) and four products containing a combination of the active ingredients s-methoprene and d-phenothrin (Hartz UltraGuard Pro Flea and Tick Treatment for Dogs and Puppies weighing either 2.5–6 kg, 6–14 kg, 14–28 kg, or greater than 28 kg). All eight end-use products are spot-on products used to kill fleas and ticks and reduce biting by mosquitoes.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

These products were first proposed for registration in the consultation document[1] Proposed Registration Decision PRD2012-34, *d-Phenothrin*. This Registration Decision[2] describes this stage of the PMRA's regulatory process for d-phenothrin and summarizes the Agency's decision, and the reasons for it. The PMRA received no comments on PRD2012-34. This decision is consistent with the proposed registration decision stated in PRD2012-34.

For more details on the information presented in this Registration Decision, please refer to PRD2012-34, *d-Phenothrin*, which contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[3] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value[4] when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

3 "Acceptable risks" as defined by subsection 2(2) of *Pest Control Products Act*.

4 "Value" as defined by subsection 2(1) of *Pest Control Products Act* "...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact".

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

What is d-Phenothrin?

d-Phenothrin is a pyrethroid that stimulates the nerves to keep the sodium channels of insects open beyond their normal timing thresholds, causing paralysis and eventually death of the pest.

The combination active ingredient that is present in the Hartz UltraGuard Pro Flea and Tick Treatment for Dogs and Puppies product line, s-methoprene, is an insect growth regulator that acts by mimicking the action of the juvenile hormone keeping the insect in an immature state which results in its eventual death.

Health Considerations

Can Approved Uses of d-Phenothrin Affect Human Health?

Products containing d-phenothrin are unlikely to affect your health when used according to label directions.

Potential exposure to d-phenothrin (Sumithrin Technical Grade) may occur when handling and applying the end-use products. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose where no effects are observed. The health effects noted in animals occur at doses more than 100-times higher (and often much higher) than levels to which humans are normally exposed when pesticide-containing products are used according to label directions.

In laboratory animals, the technical grade active ingredient d-phenothrin was slightly acutely toxic by the inhalation route of exposure; consequently, the hazard signal words "CAUTION-POISON" are required on the label. It was of low acute toxicity by the oral and dermal routes, minimally irritating to the eyes, not irritating to the skin, and did not cause an allergic skin reaction.

The end-use products Hartz UltraGuard Flea & Tick Treatment for Dogs and Puppies, and Hartz UltraGuard Pro Flea and Tick Treatment for Dogs and Puppies were of low acute toxicity via the oral and dermal routes of exposure in laboratory animals. They were not irritating to the eyes or skin and did not cause an allergic skin reaction. When administered to adult and young dogs, no adverse effects were observed at doses greatly exceeding those specified on the product labels.

There was no evidence to suggest that d-phenothrin damaged genetic material and it is not considered to be a potential human carcinogen. Although d-phenothrin exerts its action on the nervous system, there was little evidence of neurotoxicity. There was no indication that d-phenothrin caused damage to the immune system or affected the ability to reproduce. Health effects in animals given repeated doses of d-phenothrin included effects on the liver, adrenals and kidneys.

When given to pregnant or nursing rats, d-phenothrin caused slight, transient decreases in body weight of the young animal at doses which were not toxic to the mother, suggesting that the young were slightly more sensitive to d-phenothrin than the adult animal. Effects on the developing fetus (malformations) were noted following administration of d-phenothrin to pregnant rabbits. These effects occurred at doses which were also toxic to the mother.

The risk assessment protects against the effects of d-phenothrin by ensuring that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests.

Risks in Residential and Other Non-Occupational Environments

Residential risks are not of concern when Hartz UltraGuard Flea and Tick Treatment for Dogs and Puppies, and Hartz UltraGuard Pro Flea and Tick Treatment for Dogs and Puppies products are used according to label directions and instructions.

Exposure to d-phenothrin can occur when adults and youth handle these end-use products, and can come in direct contact with d-phenothrin residues on the skin. Adults, youth, and children can come in direct contact with d-phenothrin residues on the skin when contacting treated pets. In addition, children can ingest residues by hand-to-mouth activity after contacting treated dogs.

Residential exposures (application and postapplication) to the end-use products are not expected to result in unacceptable risk when these products are used according to label directions. Precautionary and hygiene statements on the label are considered adequate to protect individuals from unnecessary risk due to treatment or postapplication exposures.

Occupational Risks from Handling Hartz UltraGuard Pro Flea and Tick Treatment for Dogs and Puppies, and Hartz UltraGuard Flea and Tick Treatment for Dogs and Puppies Products

Hartz UltraGuard Pro Flea and Tick Treatment for Dogs and Puppies, and Hartz UltraGuard Flea and Tick Treatment for Dogs and Puppies products are domestic products; therefore, no occupational assessments were conducted.

No occupational assessments were conducted.

For bystanders, exposure is expected to be much less than that for workers and is considered negligible. Therefore, health risks to bystanders are not of concern.

Environmental Considerations

An environmental assessment is not required for applications to register spot-on products for use on companion animals as environmental exposure is negligible.

Value Considerations

What Is the Value of the Hartz UltraGuard Flea & Tick Treatment for Dogs and Puppies line of products and the Hartz UltraGuard Pro Flea and Tick Treatment for Dogs and Puppies line of products?

Hartz UltraGuard Flea & Tick Treatment for Dogs and Puppies and Hartz UltraGuard Pro Flea and Tick Treatment for Dogs and Puppies are spot-on products used to kill fleas and ticks and reduce biting by mosquitoes for up to 30 days on dogs and puppies over 12 weeks of age.

The Hartz UltraGuard Flea & Tick Treatment for Dogs and Puppies line of products kills fleas and ticks and reduces biting by mosquitoes for up to 30 days on dogs and puppies over 12 weeks of age. These products only target the flea adults. There are four (4) products available to treat the various sizes of dogs (i.e. 2.5–6 kg, 6–14 kg, 14–28 kg, over 28 kg).

The Hartz UltraGuard Pro Flea and Tick Treatment for Dogs and Puppies line of products kills fleas and ticks and reduces biting by mosquitoes for up to 30 days on dogs and puppies over 12 weeks of age. In addition to killing adult fleas using d-phenothrin, these products contain the insect growth regulator, s-methoprene, to kill the eggs and larvae of fleas. Without s-methoprene, the product would only target the adults. There are four (4) products available to treat the various sizes of dogs (i.e. 2.5–6 kg, 6–14 kg, 14–28 kg, over 28 kg).

Measures to Minimize Risk

Registered pesticide product labels include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions are required by law to be followed.

The key risk-reduction measures on the labels of the four Hartz UltraGuard Flea & Tick Treatment for Dogs and Puppies end-use products and the four Hartz UltraGuard Pro Flea and Tick Treatment for Dogs and Puppies end-use products to address the potential risks identified in this assessment are as follows:

Key Risk-Reduction Measures

Human Health

The hazard signal words "CAUTION-POISON" are required on the label

In the Precautions section, in addition to the statements "Causes moderate eye irritation" and "Avoid contact with eyes or clothing", the labels of the end-use products must include, "Wash hands, and any other skin that came into contact with the product, thoroughly with soap and water after handling or applying, and before eating, drinking, chewing gum or using tobacco."

As these products are a liquid formulation and a small volume is being used, there is no concern from exposure by the inhalation route.

Other Information

The relevant test data on which the decision is based (as referenced in PRD2012-34) are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

Any person may file a notice of objection[5] regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of the Health Canada's website (Request a Reconsideration of Decision, healthcanada.gc.ca/pmra) or contact the PMRA's Pest Management Information Service.

[5] As per subsection 35(1) of the *Pest Control Products Act*.